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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,092	02/27/2001	Marcus Keep	30-200P	1549

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,092	KEEP ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks filed 7/21/03 are acknowledged, entered and considered. In view of Applicant's request claims 1-3 and 8 have been amended and claims 9 and 10 have been added. Thus, claims 1-10 are now pending in the application. The objection to the abstract and the rejection under 35 U.S.C. 112, second paragraph for claims 1 and 8 are withdrawn in view of Applicant's amendment and remarks filed 7/21/03. However, the rejection under 35 U.S.C. 112, second paragraph for claims 3-7 and newly submitted claim 10 (depends on claim 3) is maintained. Also, the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record including newly submitted claims 9 and 10 are maintained for the same reasons discussed in the previous Office action.

CLAIMS REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3-7 and newly submitted claim 10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that Applicant has not amended nor argued the rejected claims 3-6 in the previous Office action under 35 U.S.C. 112, second paragraph. Thus, since claim 7 and newly submitted claim 10 depend on rejected claim 3, the previous rejection is reiterated as follows:

Claims 3-6 are indefinite in the recitation "compromises" The claims have been read as if they say, "Comprises". (See e.g., claim 8, which recites "comprises"). It is believed to be typographical error. Appropriate correction is required.

CLAIM REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al., (Int. Arch. Allergy. Immunol., Vol. 116, pp. 284-287, 1998).

Lebel et al., disclose a composition comprising a cyclosporin dissolved in dimethyl sulfoxide (DMSO) wherein the cyclosporin is cyclosporin A. To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g., pages 284 and 286) and anticipates claims 1 and 2.

4. Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kessler et al., (Biochemical Pharmacology, Vol. 40, No. 1, pp. 169-173, 1990).

Kessler et al., disclose a composition comprising a cyclosporin dissolved in polar solvent DMSO wherein the cyclosporin is cyclosporin A. To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g., pages 172-172) and anticipates claims 1 and 2.

CLAIMS REJECTION-35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-8 and newly submitted claims 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., (Int. Arch. Allergy. Immunol., Vol. 116, pp. 284-287, 1998) taken with Falk et al., (U.S. Patent No. 5,827,834).

Lebel et al., disclose a composition comprising a cyclosporin dissolved in dimethyl sulfoxide (DMSO) wherein the cyclosporin is cyclosporin A. To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g., pages 284 and 286). The reference of Lebel et al., differs from claims 3-10 in failing to teach methods for administering said cyclosporin and DMSO solution by injection into the cerebrospinal fluid, intra-ocular, intravestibular, into adjacent to the brain, or spinal cord, or intravenous, intraarterial, intraparenchymal spaces or orally, rectally, nasally or dermally to a patient wherein the cyclosporin is cyclosporin A, or functional derivatives, metabolites, variants or salts thereof, and an article of manufacture comprising packaging material and pharmaceutical agent wherein said pharmaceutical agent comprises DMSO and cyclosporin formulation thereof.

The prior art of Falk et al., (U.S. Patent No. 5,827,834) clearly teaches the method of administering a medicinal agent in general which includes immunosuppressant such as cyclosporins in treating a disease or condition in mammals (See e.g., col. 10, lines 3 to 28). The medical agent comprises methyl sulfoxide (DMSO) as a carrier transport-type molecule in an injectable formulation. Thus, combinations and formulations (for example an injectable formulation) are provided for administration to a mammal for the treatment of a disease or condition (See e.g., col. 10, lines 3 to 6), which combinations or formulations employ or incorporate as the case may be a therapeutically effective non-toxic amount of a medicinal and/or therapeutic agent to treat disease or condition for example a free radical scavenger or anti-cancer agent or anti-viral agent, or anti-bacterial agent, or analgesic or immunosuppressants (for example cyclosporins) etc. (See e.g., col. 10, lines 6-28), sufficient to facilitate the agent's penetration through the tissue (including scar tissue), at the site to be treated through the cell membranes into the individual cell to be treated (See e.g., col. 10, lines

34-37). When such combinations and formulations are administered to patients suffering from disease or condition, the disease or condition is improved. Further, the formulation can be administered among other methods, intravenously, intra arterially, intraperitoneally, intrapleurally, transdermally, on the skin (topically), rectally, orally or by direct injection (for example into a tumor, into an abscess or similar disease focus i.e., this statement may encompass cerebro spinal fluid space or adjacent to the brain or spinal cord) (See e.g., col. 10, lines 41-44). Also, the patent shows the administration of pharmaceutical agent in combination with DMSO in patients suffering from brain tumors resulted in reduction of swelling in acute brain and spinal edema. Thus, clearly showing the use of DMSO as a carrier/penetrating agent in a medicinal formulation wherein the medicinal agent or formulation could be the combination of DMSO and any agent of interest which may include cyclosporins (See e.g., abstract, cols. 3-4, cols. 10-12, col. 17, Cases I, III and IX of '834 patent) as directed to claims 3-6. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Lebel et al., with Falk et. al. patent in order to administer cyclosporin and DMSO by any one of the modes of administration recited in claims 3-6 and 10. The artisan of ordinary skill in the art utilizing the methods of Falk et. al., patent (i.e., the secondary reference) would have obtained the improvement when such combinations and formulations (as disclosed in the primary reference) are administered to patients suffering from the disease or condition.

With respect to claim 7, the method requires administering cyclosporin A, or functional derivatives, metabolites, variants or salts thereof. Given the teachings of the secondary reference of Falk et al., one of ordinary skill in the art would be able to adapt the above scheme of applying a specific cyclosporin such as functional derivatives of cyclosporin, metabolites of cyclosporin, variants of cyclosporin or salts thereof because

the secondary reference disclose cyclosporins in general without specifying particular ones as disclosed in the primary reference (i.e., cyclosporin A). Further, such features (i.e., using cyclosporins in general) are known or suggested in the art, as seen in the secondary reference, and including such features into the composition (only cyclosporin A) of the primary reference of Lebel et al., (See e.g., abstract) would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

With respect to claims 8 and 9, an article of manufacture comprising packaging material and pharmaceutical agent or formulation claimed; but, where the above reference differs from claims 8 and 9 in not teaching *per se* the formulation claimed in a packaging material. However, it is the Examiner's position that it would have been obvious to package the composition required for the method into packaging material and/or kit format of the well-known commercial expediency of dong so. Therefore, in view of the above, in view of the combined teachings of the prior art, and in the absence of evidence to the contrary, modifications such as the selection of an appropriate cyclosporin and formulations of packaging material and/or kit thereof, would have resulted in the claimed invention which was *prima facie* obvious to make and use at the time it was made.

ARGUMENTS ARE NOT PERSUASIVE

6. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Lebel et al., (Int. Arch. Allergy. Immunol., Vol. 116, pp. 284-287, 1998).

Applicant's arguments filed 7/21/03 have been fully considered but they are not persuasive. Applicant's arguments that the reference of Lebel et al. can not anticipate the instant invention because the reference fails to disclose the elements in the instantly claimed invention, i.e., pharmaceutical composition that can be administered to animals (intended use) is not persuasive. Contrary to Applicant's arguments the reference of Lebel et al. discloses a composition comprising a cyclosporin dissolved in DMSO wherein the cyclosporin is cyclosporin A. Thus, clearly disclosing the elements recited in claims 1 and 2 (i.e., cyclosporin A and DMSO). To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition. The reference does not disclose as argued by Applicant, but not recited in the composition claims 1 and 2, the intended use of the a pharmaceutical composition that can be administered to animals or humans. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 70, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old

composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

It is noted that claim 1 has been amended to recite a particular minimal concentration of cyclosporin in the pharmaceutical composition, however, with respect to the limitation (i.e., the concentration of cyclosporin is at least 0.1% by weight of the total composition); this limitation has no support in the instant disclosure because Applicant has not shown support for the claimed limitation as demonstrated infra in the rejection under 35 U.S.C. 112, first paragraph for new matter. Nevertheless, even if this limitation is incorporated in the claim, it would have been within the purview of one of ordinary skill in the art to optimize the required concentration of cyclosporin for the intended purpose of using such concentration in pharmaceutical formulation that can be administered to animals or humans. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 1 and 2 as drafted.

7. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Kessler et al., (Biochemical Pharmacology, Vol. 40, No. 1, pp. 169-173, 1990).

Applicant's arguments that the reference of Kessler et al. can not anticipate the instant invention because the reference fails to disclose the elements in the instantly claimed invention, i.e., pharmaceutical composition that can be administered to animals (intended use) is not persuasive. Contrary to Applicant's arguments the reference of Kessler et al discloses a composition comprising a cyclosporin dissolved in polar

solvent DMSO wherein the cyclosporin is cyclosporin A. Thus, clearly disclosing the elements recited in claims 1 and 2 (i.e., cyclosporin A and DMSO). To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition. The reference does not disclose as argued by Applicant, but not recited in the composition claims 1 and 2, the intended use of the a pharmaceutical composition that can be administered to animals or humans. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 70, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

It is noted that claim 1 has been amended to recite a particular minimal concentration of cyclosporin in the pharmaceutical composition, however, with respect to the limitation (i.e., the concentration of cyclosporin is at least 0.1% by weight of the total composition); this limitation has no support in the instant disclosure because

Applicant has not shown support for the claimed limitation as demonstrated infra in the rejection under 35 U.S.C. 112, first paragraph for new matter. Nevertheless, even if this limitation is incorporated in the claim, it would have been within the purview of one of ordinary skill in the art to optimize the required concentration of cyclosporin for the intended purpose of using such concentration in pharmaceutical formulation that can be administered to animals or humans. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 1 and 2 as drafted.

8. The rejection of claims 3-8 and newly submitted claims 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., (Int. Arch. Allergy. Immunol., Vol. 116, pp. 284-287, 1998) taken with Falk et al., (U.S. Patent No. 5,827,834).

Applicant's arguments that the primary reference of Lebel et al. does not teach or disclose or suggest an *in vivo* study on whole organism, and does not suggest that the *in vitro* cyclosporin solution be adapted for use in animals or humans for any purpose. Rather, Lebel et al. disclose an *in vitro* study on dissociated nasal polyp cells in a test tube. Further, Applicant notes that nowhere the reference of Lebel et al. suggests that cyclosporin-DMSO pharmaceutical drug be used in humans or animals is unpersuasive. Contrary to Applicant's arguments as discussed in the rejection under 35 U.S.C. 102(b) above, the prior art of Lebel et al. disclose a composition comprising a cyclosporin dissolved in DMSO wherein the cyclosporin is cyclosporin A. To the extent that cyclosporin dissolved in DMSO is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g., pages 284 and 286). The reference of Lebel et al. differs from claims 3-10 in failing to teach methods for administering said cyclosporin

and DMSO solution by injection into the cerebrospinal fluid, intra-ocular, intravestibular, into adjacent to the brain, or spinal cord, or intravenous, intraarterial, intraparenchymal spaces or orally, rectally, nasally or dermally to a patient wherein the cyclosporin is cyclosporin A, or functional derivatives, metabolites, variants or salts thereof, and an article of manufacture comprising packaging material and pharmaceutical agent wherein said pharmaceutical agent comprises DMSO and cyclosporin formulation thereof.

The prior art of Falk et al., (U.S. Patent No. 5,827,834) clearly teaches the method of administering a medicinal agent in general which includes immunosuppressant such as cyclosporins in treating a disease or condition in mammals (See e.g., col. 10, lines 3 to 28). The medical agent comprises methyl sulfoxide (DMSO) as a carrier transport-type molecule in an injectable formulation. Thus, combinations and formulations (for example an injectable formulation) are provided for administration to a mammal for the treatment of a disease or condition (See e.g., col. 10, lines 3 to 6), which combinations or formulations employ or incorporate as the case may be a therapeutically effective non-toxic amount of a medicinal and/or therapeutic agent to treat disease or condition for example a free radical scavenger or anti-cancer agent or anti-viral agent, or anti-bacterial agent, or analgesic or immunosuppressants (for example cyclosporins) etc. (See e.g., col. 10, lines 6-28), sufficient to facilitate the agent's penetration through the tissue (including scar tissue), at the site to be treated through the cell membranes into the individual cell to be treated (See e.g., col. 10, lines 34-37). When such combinations and formulations are administered to patients suffering from disease or condition, the disease or condition is improved. Further, the formulation can be administered among other methods, intravenously, intra arterially, intraperitoneally, intrapleurally, transdermally, on the skin (topically), rectally, orally or by direct injection (for example into a tumor, into an abscess or similar disease focus i.e.,

this statement may encompass cerebro spinal fluid space or adjacent to the brain or spinal cord) (See e.g., col. 10, lines 41-44).

Further, Applicant asserts that hyaluronic acid is used to facilitate the transfer of DMSO to reduce acute brain and spinal edema. Thus, DMSO is thought to be the active ingredient in Falk '834 patent. Contrary to Applicant's assertion, the secondary reference of '834 patent shows the administration of pharmaceutical agent in combination with DMSO in patients suffering from brain tumors resulted in reduction of swelling in acute brain and spinal edema. Thus, clearly showing the use of DMSO as a carrier/penetrating agent in a medicinal formulation wherein the medicinal agent or formulation could be the combination of DMSO and any agent of interest which may include cyclosporins (See e.g., abstract, cols. 3-4, cols. 10-12, col. 17, Cases I, III and IX of '834 patent) as directed to claims 3-6. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Lebel et al., with Falk et. al. patent in order to administer cyclosporin and DMSO by any one of the mode of administration recited in claims 3-6 and 10. The artisan of ordinary skill in the art utilizing the methods of Falk et. al., patent (i.e., the secondary reference) would have obtained the improvement when such combinations and formulations (as disclosed in the primary reference) are administered to patients suffering from the disease or condition.

With respect to the limitation of the concentration of cyclosporin (i.e., the concentration of cyclosporin is at least 0.1% by weight of the total composition); it is noted that claim 1 has been amended to recite a particular minimal concentration of cyclosporin in the pharmaceutical composition; however, this limitation has no support

in the instant disclosure because Applicant has not shown support for the claimed limitation as demonstrated infra in the rejection under 35 U.S.C. 112, first paragraph for new matter. Nevertheless, even if this limitation is incorporated in the claim, it would have been within the purview of one of ordinary skill in the art to optimize the required concentration of cyclosporin for the intended purpose of using such concentration in pharmaceutical formulation that can be administered to animals or humans.

In regard to Applicant's arguments that in proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. Further, Applicant continues by stating that the Examiner's conclusion of obviousness is based on improper reasoning and mischaracterization of the art. No suggestion to modify the cited references has been found in the cited references or pointed out to Applicant from the general knowledge of one of ordinary skill in the art. For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness, as required by 35 U.S.C. 103(a) is unpersuasive. Contrary to Applicant's arguments, in view of the combined teachings of the prior art and in view for the reasons discussed above; one of ordinary skill in the art would have been motivated at the time the invention was made to employ or use the subject composition in combination with other materials to provide a wide variety of applications or may be tailored for specific applications in the manner claimed. Thus, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would

have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

NEW GROUND OF REJECTION

The following is a new ground of rejection necessitated by Applicant's amendment.

CLAIMS REJECTION-35 U.S.C. § 112 1st PARAGRAPH

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 1 as amended on 7/21/03 contains new matter because the original specification does not appear to support "wherein the concentration of **cyclosporin** is at least 0.1% by weight of the total composition". The specification on page 6, lines 21-22 state that "The formulary drug generally contains from 0.1% to 90%

of the treatment medications by weight of the total composition". Thus, independent claim 1 has no support for the **concentration of cyclosporin of at least 0.1%** from the original disclosure because there is no disclosure in the specification as now claimed. Thus, Applicant respectfully requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure

ACTION IS FINAL, NECESSITATED BY AMENDMENT

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM

December 1, 2003